



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

05 FEB 1993

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Mole Medtm Castor Oil, EPA File Symbol 64439-R, Chem code
031608, Candidate Reduced Risk Pesticide for Reduced
Data Requirements

FROM: Anthony F. Maciorowski, Chief *Anthony F. Maciorowski*
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TO: Robert Forrest PM-14 & Daniel Peacock
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Mole Med castor oil was classified by the Agency as a biochemical pesticide in February 1992 for the following reasons:

1. The source of the castor oil is natural being from the beans of the castor-oil plant, *Ricinus communis*, native to India.
2. the castor oil is of food grade and
3. the mode of action is nontoxic.

The castor oil used as the active ingredient (A.I.) of Mole Med is U.S. Pharmacopeia (USP) grade refined to remove the characteristic odor and taste. Castor oil has a long history of medicinal use as a cathartic or laxative. Mole Med allegedly acts as a repellent because of possible irritant effects on moles according to the applicant.

The Tier 1 ecological effects data requirements of CFR 40 158.690, Table (d) Biochemical pesticides non-target organism and environmental data requirements are the following:

<u>Kind of data required</u>	<u>Guideline reference No.</u>
Avian acute oral, bobwhite quail	154-6/71-1
Avian dietary, bobwhite quail	154-7/71-2
Freshwater fish LC ₅₀ , rainbow trout	154-8/72-1
Freshwater invertebrate LC ₅₀	154-9/72-2



Castor oil meets criteria of the June 1992 draft Guidance for Making Determinations to Reduce Data Requirements. The following criteria from the draft Guidance are generally met by castor oil:

GROUP I (must meet two of three conditions)

- a. Listed as GRAS (FDA - Generally Recognized as Safe)
- b. Recognized as a common human food or significant component of a common food.
- c. Widely distributed in commerce and available throughout the US for nonpesticidal uses.

and GROUP II (must meet both conditions)

- a. No 6(a)2 data submitted that shows significant adverse effects.
- b. OPP is not aware of any significant adverse effects of the pesticide to humans or the environment associated with its use as a pesticide.

and GROUP III (must meet at least two conditions)

- a. Negligible human and environmental exposure to the pesticide as a result of the proposed use pattern.
- b. Nontoxic mode of action for target pest.
- c. Structurally related or structurally equivalent to a compound for which there are data to indicate no adverse effects to humans or the environment.
- d. The pesticide can be presumed nonpersistent based on knowledge of its composition.

According to the draft reduced data requirements Guidance, products in this category would be exempt from the generic toxicology, ecological effects and environmental fate data requirements for the active ingredient as presently set forth in CFR 40 Part 158. Since castor oil generally meets the criteria, it is a candidate for reduced data requirements. Consequently, the above nontarget organism data requirements could be waived under the provisions of the draft.

The registrant's representative submitted waiver requests on 01/06/93 for 154-6 Avian acute oral, 154-7 Avian dietary, 154-8 Freshwater fish LC₅₀ and 154-9 Freshwater invertebrate LC₅₀ data requirements. Adequate rationale was provided based on minimal exposure to birds, lack of rat oral toxicity, FDA approval as a food additive and medicine, low solubility and biodegradability of castor oil which is 87% ricinoleic acid.

In consideration that castor oil generally meets the criteria of the draft guidance for reduced data requirements and the data waiver request rationales submitted by the registrant, it is recommended that the nontarget organism data requirements be waived.

Since the registrant provided information that the solubility of castor oil has been tabulated at various levels between 100 and 300 mg/l, there is an undetermined possibility that some aquatic organisms may be adversely affected. To mitigate such risks, it is recommended that the label state:

ENVIRONMENTAL HAZARDS

Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters.

Also, in the Mole Med labeling under directions for use, change: "Then water in for 25 minutes." to: "Then soak in with water in for about 25 minutes. Avoid using excess water that may flow off turf into streams, ponds, gutters or storm sewers."